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510(k) Summary – K100724

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92

Establishment Reg. Number: 1038806

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Date Prepared: May 19th, 2010

Trade/Proprietary Name: Full OSSEOTITE® Certain® II Dental Implant

Common/Usual Name: Dental Implant

Classification Name: Endosseous Dental Implant

Device Classification/Code: Class II - 21 CFR §872.3640 / DZE

Predicate Devices: K063341 BIOMET 3i OSSEOTITE® Dental Implant System
K062636 BIOMET 3i Dental Implants

Indications for Use: BIOMET 3i Dental Implants are intended for surgical placement in either jaw and used for anchoring or supporting single- and multiple-unit prostheses. BIOMET 3i Dental Implants can be immediately loaded when primary stability and proper occlusion have been established.

Statement of Equivalence: Full OSSEOTITE® Certain® II Dental Implants are substantially equivalent to BIOMET 3i's OSSEOTITE® Dental Implants which have been previously cleared in K063286 and K063341.

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Technological Characteristics:

Criteria	Predicate BIOMET *3i* Dental Implant(s)	Proposed BIOMET *3i* Full OSSEOTITE® Certain® II Dental Implants
Implant Lengths	Ø3.25: 8.5, 10.0, 11.5, 13.0, 15.0, 18.0mm Ø4.0: 8.5, 10.0, 11.5, 13.0, 15.0, 18.0, 20.0mm Ø5.0: 8.5, 10.0, 11.5, 13.0, 15.0mm Ø6.0: 8.5, 10.0, 11.5, 13.0, 15.0mm	Ø3.25: 8.5, 10.0, 11.5, 13.0, 15.0, 18.0mm Ø4.0: 8.5, 10.0, 11.5, 13.0, 15.0, 18.0, 20.0mm Ø5.0: 8.5, 10.0, 11.5, 13.0, 15.0mm Ø6.0: 8.5, 10.0, 11.5, 13.0, 15.0mm
Implant Body Diameters	Ø3.25, 4.0, 5.0, 6.0mm	Ø3.25, 4.0, 5.0, 6.0mm
Seating Platform Diameter	Ø3.4, 4.0, 5.0, 6.0mm	Ø3.4, 4.0, 5.0, 6.0mm
Material	• Commercially Pure Titanium • Titanium Alloy	Commercially Pure Titanium
Biocompatible	Yes	Yes
Thread Design	• 60° thread & 0.6mm pitch (Straight-Wall) • 60° thread & 0.9mm pitch (Straight-Wall) • 35° thread & 0.8mm pitch (Tapered)	• 60° thread & 0.6mm pitch (Straight-Wall) • 35° thread & 0.8mm pitch (Straight-Wall)
Implant Design	Straight-walled implant body	Straight-walled implant body
Self Tapping Feature	Incremental Cutting Edge (I.C.E.) with apical taper	Incremental Cutting Edge (I.C.E.) with apical taper
Implant Surface	• OSSEOTITE® • Full OSSEOTITE®	Full OSSEOTITE®
Color-Coding	• Anodized Seating Surface • Color-Coded Labeling	• Anodized Seating Surface • Color-Coded Labeling
Packaging	Packaged in sterile tray with cover screw	Packaged in sterile tray with cover screw
Sterilization	Sterile (Gamma Irradiation)	Sterile (Gamma Irradiation)
Shelf Life	5 Years	5 Years
Implant Placement Protocol	Per BIOMET *3i* Surgical Catalog CATSM	Per BIOMET *3i* Surgical Catalog CATSM
Implant/Abutment Mating Connection	Internal Hexagon Connection	Internal Hexagon Connection
Mating Components	All BIOMET *3i* Certain® Restorative Components	All BIOMET *3i* Certain® Restorative Components

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BIOMET 3i has established Design Verification Testing to be performed as well as acceptance criteria. These tests include cyclic fatigue and static angle bend testing as well as additional design verification tests to ensure proper device functioning. FDA Guidance Document – Special Control Class II Root-Form Dental Implants (May 2004) is used as the basis for design verification testing.

Proposed Design(s) Vs. Predicate BIOMET 3i Endosseous Implant Design(s):

• Full OSSEOTITE® Certain® II Dental Implants are manufactured from the same Commercially Pure Titanium material as BIOMET 3i External Hex implants and have the same indications and usage as predicated BIOMET 3i implants.

•Ø3.25 & Ø4.0mm diameter implants utilize the same thread design (pitch, thread angle, minor/major diameters) as predicate BIOMET 3i Straight-Walled implant devices.

•Ø5.0 & Ø6.0mm diameter implants utilize the same thread design (pitch & thread angle) as predicate BIOMET 3i Tapered Implants and the same thread dimensions (minor/major diameters) as predicate BIOMET 3i Straight-Walled implant devices.

• Full OSSEOTITE® Certain® II dental implants have less apical taper shorter apical cutting flute heights.

•Since all BIOMET 3i Endosseous Dental Implants are tested according to FDA Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, the comparison of performance criteria between the proposed design and the predicates is evident.

Conclusion:

The BIOMET 3i Full OSSEOTITE® Certain® II Dental Implants and predicate designs have the same intended use, indications, similar technological characteristics and principles of operation.

The differences noted above do not present new issues of safety or effectiveness for the Full OSSEOTITE® Certain® II Dental Implants. Design verification and performance testing to verify and/or validate the changes has been conducted when risk analysis indicated mitigation with testing necessary. The results of the performance testing demonstrate that the BIOMET 3i Full OSSEOTITE® Certain® II Dental Implants are substantially equivalent to their predicate designs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Re: K100724
Trade/Device Name: Full OSSEOTITE® Certain® II Dental Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 23, 2011
Received: March 24, 2011

Dear Mr. Cabrera:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K100724

Device Name: Full OSSEOTITE® Certain® II Dental Implant

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Prescription Use __X___ **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) **AND/OR** **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K100724